Impact of Multiple Consecutive Donnings on Filtering Facepiece Respirator Fit

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Project Goal

- Provide preliminary data to better understand the impact of multiple donnings on the fit of NIOSH-certified N95 particulate filtering facepiece respirators (FFRs).

Background

- Reuse of N95 FFRs is generally limited by considerations of hygiene, damage, and breathing resistance[1]. Because reuse can be practiced in certain scenarios, an assessment of how fit changes over multiple consecutive donnings is necessary.
- Previous studies[2,3] calculated average FFR fit factors over multiple donnings, but did not assess the trend in fit factor change.

Methods

- Six NIOSH-certified N95 FFR models were evaluated.
  - 3M 8000, 3M 8210, Moldex 2200, 3M 1860*, 3M 1870*, Kimberly Clark PFR95-270 (46767)*.

*denotes surgical N95 respirators cleared by the U.S. Food and Drug Administration)

Figure 1. Test Subject Performing a Fit Test

- A Model 8020A PORTACOUNT® Fit Tester and Model 8095 N95 Companion™ (TSI, Inc., Shoreview, MN) were used for fit testing.
- Ten experienced subjects tested each respirator model.
  - Subjects were first qualified for at least one model by passing the standard OSHA-accepted quantitative fit test (i.e., achieving a fit factor (FF) ≥ 100).
  - A total of 17 subjects (10 men and 7 women) participated in the study to obtain 10 qualified subjects per model. This resulted in different cohorts of subjects for different models.
- Each subject performed up to 20 abbreviated fit tests for each of two FFR samples tested per model.
  - The abbreviated (121-sec, 6-exercise) fit test protocol was used to determine the fit factor of each donning.
  - Testing was terminated before the 20th donning in the event of three consecutive FF failures (FF< 100) or a broken head strap.
    - If testing was terminated, all successive 'no tests' before the 20th donning were counted as failures in the data analysis.
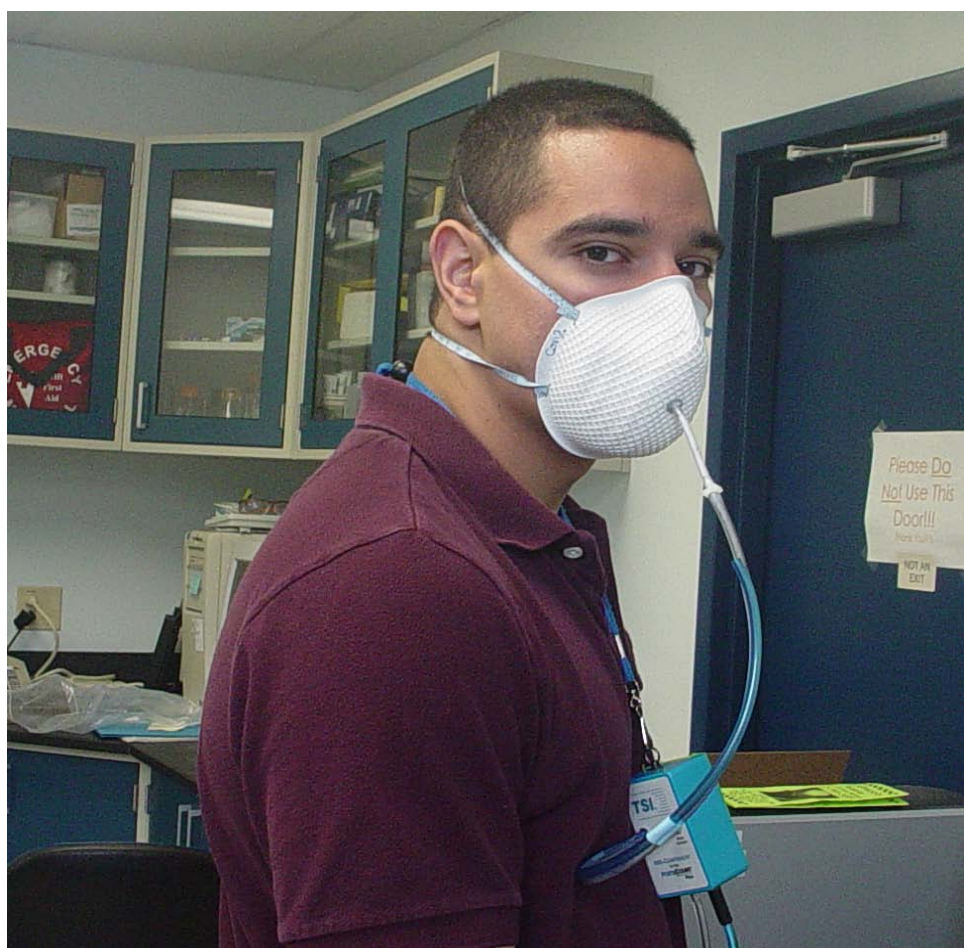
Methods (cont.)

- One model experienced five broken metallic nosepiece adjustment devices which was unexpected, however testing was continued to evaluate the effect of the damage on FFR fit.
- The manufacturers' user seal check (USC) and donning procedures were followed for all tests.

Results and Discussion

- Incidents of 'Terminal Failures' (three consecutive FFs < 100, broken head straps, and broken nosepiece devices) are shown in Table 1. The frequency of each incident type varied by model.
- The 'Passing Rates' at each donning for each FFR model are shown in Fig 2. 'Passing Rate' decreases over successive donnings; however, after 20 donnings, 55-65% of subjects passed the fit test.
- At donning #20, 30-65% of fit tests achieved a FF of 200 (the upper limit of the instrument) indicating that good levels of fit are achievable for some test subject / FFR model combinations.
- Mean 'Passing Rate' for donning groups #1-5, #6-10, #11-15, and #16-20 show that the highest percentage of fit was observed for donnings #1-5, which is likely from little wear imparted on FFR materials compared to later donnings (Table 2).
- The cumulative failure rate of three consecutive failing FFs (< 100) for all six models combined are shown in Fig 3. A rate of 9.2% is shown at donning #6; when the fit test error rate of 3.3% (Donning #1) is subtracted, the resulting rate for Donning #6 is >5% suggesting that some limitation on the number of multiple donnings for workplace use may be appropriate.

Table 1. Frequency of 'Terminal Failures' by Model

Model[†]	3 Consecutive FF < 100	Head strap Break	Nosepiece Break
N95-A	6	0	0
N95-B	7	0	0
N95-C	4	4	0
SN95-D	1	0	5*
SN95-E	2	4	0
SN95-F	4	0	0
Total	24	8	5

[†]The 'SN95' notation denotes surgical N95.
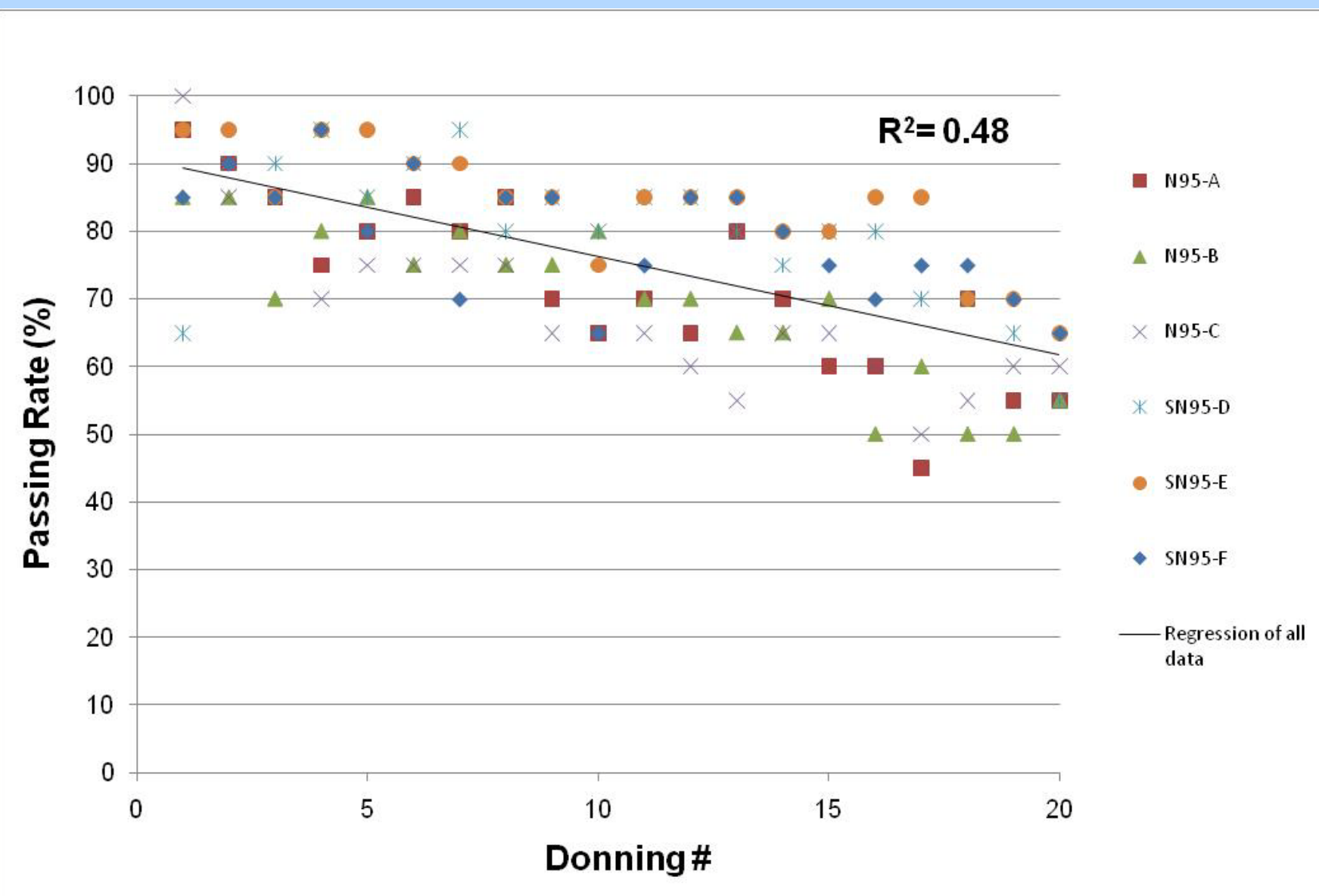* The 5 nosepiece breaks also experienced 3 consecutive fit factors <100.

Fig 2. 'Passing Rate' for each FFR Model

Results (cont.)

Table 2. Mean 'Passing Rate' Results by FFR Model

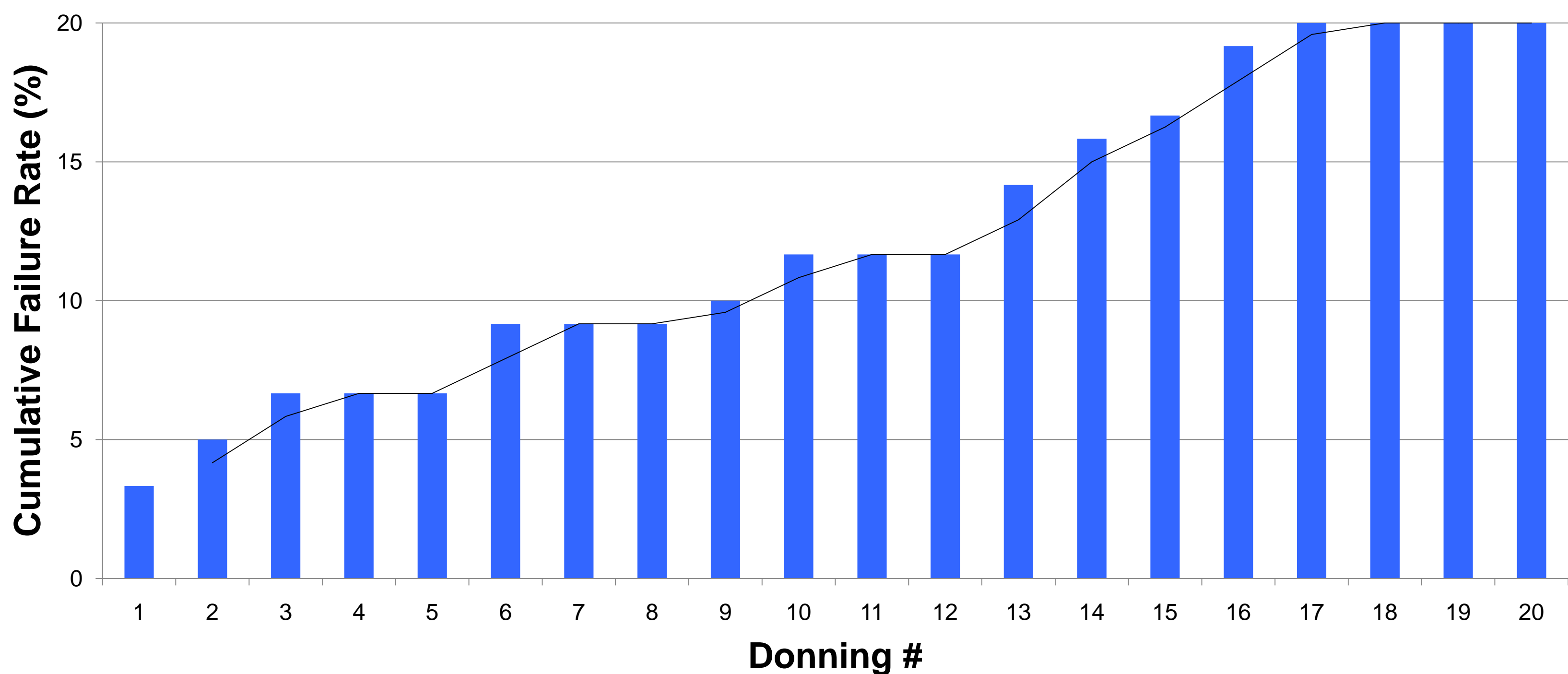| Donning #	N95-A (%)	N95-B (%)	N95-C (%)	SN95-D (%)	SN95-E (%)	SN95-F (%)
1-5	85 +/- 8	81 +/- 7	83 +/- 12	85 +/- 12	93 +/- 4	87 +/- 6
6-10	77 +/- 9	77 +/- 3	71 +/- 5	86 +/- 7	85 +/- 6	79 +/- 11
11-15	69 +/- 7	68 +/- 3	62 +/- 4	81 +/- 4	83 +/- 3	80 +/- 5
16-20	57 +/- 9	53 +/- 4	57 +/- 4	68 +/- 9	75 +/- 9	71 +/- 4

Figure 3. Cumulative Failure Rate of Three Consecutive Fit Factors < 100 (failing) For all Six Models Combined

Limitations

- Small number of subjects (n=10 per model) and FFR models (n=6).
- Test participants were experienced respirator test subjects. Inexperienced subjects may have performed differently.
- Results may have been different if the standard OSHA 8-exercise fit test had been used for the multi-donning fit test experiments.

Conclusions

- Multiple donnings have a model dependent impact on respirator fit.
- The data suggest that five consecutive donnings can be performed without significant occurrence of three consecutive failing FFs (< 100); however, additional research is needed to confirm these results.
- Further research is still needed to understand the effects of multiple donnings on FFR fit, especially in actual workplace settings.

References

1. National Institute for Occupational Safety and Health (NIOSH). May 2, 1997 Letter to All Users of P-Series Particulate Respirators - NIOSH Service Time Recommendations for P-Series Particulate Respirators (1997). http://www.cdc.gov/niosh/npptl/usernotices/run-050297.html
2. Coffey C.C., Lawrence R.B., Zhuang Z., Duling M.G., and D.L. Campbell: Errors Associated with Three Methods of Assessing Respirator Fit. Occup. Environ. Hyg. 3: 44-52 (2006).
3. Viscusi D.J., Bergman M.S., Novak D.A., Faulkner K.A., Powell J.B., and A.J. Palmiero: Impact of Three Biological Decontamination Methods on Filtering Facepiece Respirator Fit, Smell, Comfort, and Donning Ease. Submitted to J. Occup. Environ. Hyg. (2011).

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